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EXAMINER

BERCH, MARK L.

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 50, 59, 65-67, 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The proviso ii lacks description. Even a negative limitation requires description, Ex Parte Grasselli, 231 USPQ 393. The quotation from MPEP 2173.05(i) is noted, and as a result, proviso i is not problematic. However, this ii does not explicitly exclude either one. If H were removed from the definitions of these variables, that would not be a problem. But this proviso introduces a new concept, viz, that the definition of R4 depends on the definition of R5 and vice versa. That concept is not in the specification.

The new proviso overcomes the rejection over WO 97/16452, De Azevedo, 6316456, and Jacobsen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 50, 59, 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Norman.

The reasons were given previously; the traverse is unpersuasive. Benefit of the parent is denied because of reasons given in the above rejection. That is, these claims lack benefit of the date of the parent. Since the proviso is not in this case, it is not in the parent either.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48, 50, 56-57, 61, 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesely.

The reference discloses olomoucine, which the proviso removes from claim 1. However, the 6-(α , α -dimethylbenzylamino) derivative would be the same as the prior art, just with two extra methyls on the α carbon of the benzyl. Likewise for a benzyl with an extra methyl of the ring. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing

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homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *Ex Parte Fischer* 96 USPQ 345; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph. The utility is the same.

The traverse is unpersuasive. Applicants argue that "any substitution, even of an exceedingly minor nature, may significantly impact...." This is certainly true; indeed, any change of any type, regardless of how obvious, can have a major effect. Even the smallest structural change, a tiny variation in temperature or solvent, a minor alteration in a procedural detail, etc. can bring about a major and unexpected effect. The mere possibility of a major effect does not overturn obviousness, otherwise there would not be rejections of any type for e.g. structural obviousness. Applicants must demonstrate by suitable comparative testing, that there really is such a difference. Cf *In re Dillon*, 16 USPQ2nd 1897, 1901; *In re Hoch*, 166 USPQ 406; *Brown v. Gottshalk*, 179 USPQ 65; *In re Murch*, 175 USPQ 430. Merely stating that an unexpected effect could arise is not enough.

Applicants point to the difference in Table 2 between compound 2 with the dimethylamino and compound 3 with the trimethylamino. First, that is adding a methyl to a N atom, not to a carbon as the rejection has it. Second, that introduces a very

drastic structural change, going from a neutral compound (the tertiary amine) to a salt (the quaternary ammonium compound). A better comparison would be to compare the actual relevant olomoucine, compound 51, with compound 53, with is olomoucine having an extra two methyl groups attached to a carbon, exactly as the examiner has suggested is obvious (albeit at a different place). For cdc2, this produced a modest improvement, from 7 to 2, which certainly would motivate one to add methyl groups.

Claims 54, 55, 60 and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

The parentage is still not correct. It says "... which is a section 371 application of ..." but in fact, it is a CIP of the PCT application.

This case lacks a proper abstract; the one provided is too brief and gives no clue as to structure of the compounds. Suggested is page 57, but leaving out the last 6 words.

The scheme on page 19 is defective. The three steps must recite a reagent used, not a bare moiety. The same problem occurs on page 36. The previous traverse was unpersuasive. The scheme is simply not correct. Applicants are again urged to implement the changes which were made in 08/692012 as well, e.g. "bromalino" in the last line of page 31. which is not correct at all, as many of the same errors are here as well.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

January 9, 2004